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| FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE<br>(REV. 7-2005)   |  | ATTORNEY'S DOCKET NUMBER<br><b>DEX-0550</b>                          |
| <b>TRANSMITTAL LETTER TO THE UNITED STATES</b><br><b>DESIGNATED/ELECTED OFFICE (DO/EO/US)</b><br><b>CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>   |  | U.S. APPLICATION NO. (If known, see 37 CFR 1.5)<br><b>10/537,695</b> |
| INTERNATIONAL APPLICATION NO.<br><b>PCT/US03/38829</b>  | INTERNATIONAL FILING DATE<br><b>December 5, 2003</b> | PRIORITY DATE CLAIMED<br><b>December 5, 2002</b>                     |
| TITLE OF INVENTION<br><b>Compositions, Splice Variants and Methods Relating to Breast Specific Genes and Proteins</b>   |  |  |
| APPLICANT(S) FOR DO/EO/US<br><b>Macina et al.</b>   |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |  |
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</li> <li>11. <input type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409).</li> <li>12. <input type="checkbox"/> A copy of the International Search Report (PCT/ISA/210).</li> </ol> <p><b>Items 13 to 23 below concern document(s) or information included:</b></p> <ol style="list-style-type: none"> <li>13. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>14. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>15. <input type="checkbox"/> A <b>FIRST</b> preliminary amendment.</li> <li>16. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</li> <li>17. <input type="checkbox"/> A substitute specification.</li> <li>18. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>19. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.</li> <li>20. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>21. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).</li> <li>22. <input type="checkbox"/> Express Mail Label No.</li> </ol> |  |  |

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| U.S. APPLICATION NO (if known, see 37 CFR 1.5)<br><b>10/537,695</b>  | INTERNATIONAL APPLICATION NO.<br><b>PCT/US03/38829</b> | ATTORNEY'S DOCKET NUMBER<br><b>DEX-0550</b>                            |
| 23. Other items or information:<br>1) Copy of Notification of Missing Requirements;<br>2) Copies of Transmittal Letter dated July 10, 2006 and accompanying documents, including requisite fees in response to Notification of Missing Requirements dated May 24, 2006; and<br>3) Copy of USPTO PAIR document evidencing receipt of number (2) above.  |  |  |
| The following fees have been submitted:<br>24. <input type="checkbox"/> Basic national fee ..... \$300   |  | <b>CALCULATIONS</b> <b>PTO USE</b><br>\$                    \$0.00     |
| 25. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))<br>If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ... \$0<br>All other situations. .... \$200   |  | \$                    \$0.00<br>\$0<br>\$200                           |
| 26. <input type="checkbox"/> Search fee (37 CFR 1.492(b))<br>If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ... \$0<br>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. .... \$100<br>International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. .... \$400<br>All other situations. .... \$500 |  | \$                    \$0.00<br>\$0<br>\$100<br>\$400<br>\$500         |
| <b>TOTAL OF 24, 25 and 26 =</b>  |  | \$                    \$0.00   |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).<br>The fee is \$250 for each additional 50 sheets of paper or fraction thereof.  |  |  |
| Total Sheets   | Extra Sheets   | Number of each additional 50 or fraction thereof (round up to a whole) |
| - 100 =  | 0 /50 =  | 0  |
|  |  | x \$250.00   |
|  |  | \$                    \$0.00   |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).  |  | \$   |
| CLAIMS   | NUMBER FILED   | NUMBER EXTRA   |
| Total claims   | - 20 =   | 0  |
| Independent claims   | - 3 =  | 0  |
|  |  | x \$50.00  |
|  |  | \$                    \$0.00   |
|  |  | x \$200.00   |
|  |  | \$                    \$0.00   |
| MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00  |  | \$                    \$0.00   |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |  | \$                    \$0.00   |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.   |  | \$                    \$0.00   |
| <b>SUBTOTAL =</b>  |  | \$                    \$0.00   |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  |  | \$                    \$0.00   |
| <b>TOTAL NATIONAL FEE =</b>  |  | \$                    \$0.00   |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +  |  | \$                    \$0.00   |
| <b>No fee is required</b>  |  | \$                    \$0.00   |
|  |  | <b>Amount to be</b> \$   |
|  |  | <b>Amount to be</b> \$   |

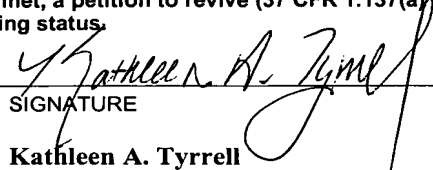
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- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
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- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1619. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Jane Massey Licata, Reg. No. 32,257  
Kathleen A. Tyrrell, Reg. No. 38,350  
Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
Telephone: (856) 810-1515  
Facsimile: (856) 810-1454

  
SIGNATURE

Kathleen A. Tyrrell

NAME

38,350

REGISTRATION NUMBER

August 18, 2006

DATE

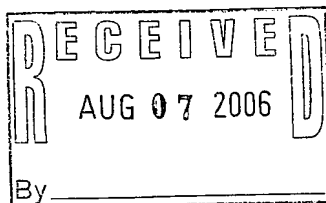


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|                             |                       |                  |
|-----------------------------|-----------------------|------------------|
| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 10/537,695                  | Roberto A MACINA      | DEX-0550         |

32800  
LICATA & TYRRELL P.C.  
66 E. MAIN STREET  
MARLTON, NJ 08053



|                               |               |
|-------------------------------|---------------|
| INTERNATIONAL APPLICATION NO. |               |
| PCT/US03/38829                |               |
| I.A. FILING DATE              | PRIORITY DATE |
| 12/05/2003                    | 12/05/2002    |

CONFIRMATION NO. 8042

371 FORMALITIES LETTER



\*OC000000019868072\*

Docket System ☒  
Status Report ☒  
Docket Book ☒

Date Mailed: 08/03/2006

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 06/06/2005
- Copy of the International Search Report filed on 06/06/2005
- Preliminary Amendments filed on 06/06/2005
- Information Disclosure Statements filed on 06/06/2005
- Biochemical Sequence Diskette filed on 06/06/2005
- U.S. Basic National Fees filed on 06/06/2005
- Specification filed on 06/06/2005
- Claims filed on 06/06/2005

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

FRANCINE YOUNG

Telephone: (703) 308-9140 EXT 215

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/537,695                  | PCT/US03/38829                | DEX-0550         |

FORM PCT/DO/EO/905 (371 Formalities Notice)



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## Available Documents

| Mail Room Date | Document   |  | Document Categor |
|----------------|--|--|------------------|
|                | Description  |  |                  |
| 08-03-2006     | Notice of DO/EO<br>Missing<br>Requirements<br>Mailed                     |  | PROSECUTION      |
| 07-17-2006     | Miscellaneous<br>Internal Document                                       |  | PROSECUTION      |
| 07-17-2006     | Fee Worksheet<br>(PTO-875)   |  | PROSECUTION      |
| 07-17-2006     | Applicant Response<br>to Pre-Exam<br>Formalities Notice                  |  | PROSECUTION      |
| 07-17-2006     | Oath or Declaration<br>filed   |  | PROSECUTION      |
| 05-24-2006     | Notice of DO/EO<br>Missing<br>Requirements<br>Mailed                     |  | PROSECUTION      |
| 06-16-2005     | CRF Sequence<br>Listing Filed  |  | PROSECUTION      |
| 06-06-2005     | Miscellaneous<br>Internal Document                                       |  | PROSECUTION      |
| 06-06-2005     | Claims Worksheet<br>(PTO-2022)   |  | PROSECUTION      |
| 06-06-2005     | Preliminary<br>Amendment   |  | PROSECUTION      |
| 06-06-2005     | Claims   |  | PROSECUTION      |
| 06-06-2005     | Applicant<br>Arguments/Remarks<br>Made in an<br>Amendment<br>Information |  | PROSECUTION      |
| 06-06-2005     | Disclosure<br>Statement (IDS)<br>Filed                                   |  | PROSECUTION      |
| 06-06-2005     | NPL Documents  |  | PROSECUTION      |
| 06-06-2005     | NPL Documents  |  | PROSECUTION      |
| 06-06-2005     | Documents<br>submitted with 371<br>Applications                          |  | PROSECUTION      |
| 06-06-2005     | Documents<br>submitted with 371<br>Applications                          |  | PROSECUTION      |
| 06-06-2005     | Documents<br>submitted with 371  |  | PROSECUTION      |

|            |  |             |
|------------|--|-------------|
|            | <u>Applications</u>                        |             |
| 06-06-2005 | <u>NPL Documents</u>                       | PROSECUTION |
| 06-06-2005 | <u>Transmittal letter</u>                  | PROSECUTION |
| 06-06-2005 | <u>Specification</u>                       | PROSECUTION |
| 06-06-2005 | <u>Claims</u>                              | PROSECUTION |
| 06-06-2005 | <u>Abstract</u>                            | PROSECUTION |
| 06-06-2005 | <u>Sequence Listing</u>                    | PROSECUTION |
| 06-06-2005 | <u>Oath or Declaration<br/>filed</u>       | PROSECUTION |
| 06-06-2005 | <u>Miscellaneous<br/>Internal Document</u> | PROSECUTION |
| 06-06-2005 | <u>Fee Worksheet<br/>(PTO-875)</u>         | PROSECUTION |

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